## **ONETOUCH**



Blood Glucose Monitoring System

Link the Effects of Food to Glucose Results



#### **Owner's Booklet**

#### Welcome to the OneTouch® family!

We know diabetes can be difficult to understand and manage. The right products and services can help make life with diabetes just a little bit easier. We hope the OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 System works well for you.

We designed this product to make testing easy and to help you manage your diabetes. You can use the meter for fast and simple tests. You can also use it to record information to go with your results.

This owner's booklet is designed to provide the information that you are looking for, when you need it. We hope you keep it handy.

Of course, you may still have questions. If you do, our Customer Service representatives would be happy to answer your call. You can reach them at 1 800 227-8862, anytime—24 hours a day. You can also obtain information at www.LifeScan.com.

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- Turning your meter on and off
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- Setting up your meter

**NOTE:** Before testing, read this owner's booklet carefully.

#### Starting the test process

#### Insert a test strip

Check the code on the test strip vial before inserting the strip. Make sure the three contact bars are facing you. Push the strip in as far as it will go. Do not bend the strip.



The meter will turn on, show a black start-up screen and then a code number. The first time you use the meter, the CAL CODE screen will display "---" instead of a number.

## Match the code displayed on the meter with the code on the test strip vial

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If the code on the meter does not match the code on the vial, press 🛆 or 🐨 to change the code. If the display changes to the APPLY BLOOD screen before you are ready, remove the strip and re-start the test process.



Press is when the numbers match.

The meter is ready for testing when the APPLY BLOOD screen appears.

#### Getting a blood sample

#### Prepare the OneTouch® UltraSoft® Blood Sampler

Remove the blue cap and put a new lancet in the sampler. Twist off the protective disk. Replace the cap and cock the sampler.



#### Get a drop of blood

Hold the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler firmly against your finger. Press the release button.



Gently squeeze and/or massage your fingertip until a round drop of blood of at least one microliter (actual size) forms on your fingertip.



#### pg. 14 Applying blood pg. 25 and reading results

#### Touch and hold the drop of blood to the narrow channel in the top edge of the test strip

Blood will be drawn into the strip. Keep holding the drop of blood to the top edge of the strip until the confirmation window is full. The meter will begin to count down from 5 to 1. Then, your blood glucose level appears on the display along with the unit of measure, and the date and time of the test.





If the test results are lower than, higher than, or not what you expect, see pages 28–29.

#### Attaching flags or comments to your results

### Add a meal flag to track different types of averages

While viewing your test result, press 📥 to get the MEAL FLAG screen.



Press 📥 or 🐨 to highlight BEFORE MEAL or AFTER MEAL.

To confirm your selection, press 💿.

The meal flag you chose will appear above the result.

If you do not wish to add a meal flag, select NO FLAG and press This will return you to the glucose result screen.

#### Add a comment

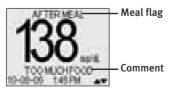
While viewing a test result, press **T** to get the COMMENT screen.



Press 📥 or 🐨 to highlight an appropriate comment.

To confirm your selection, press

The comment you chose appears below the result.



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#### Before you begin

Before using this product to test your blood glucose, carefully read this booklet and the inserts that come with the OneTouch<sup>®</sup> Ultra<sup>®</sup> Test Strips and OneTouch<sup>®</sup> Ultra<sup>®</sup> Control Solution. Take note of warnings and cautions throughout this booklet, which are identified with  $\triangle$ . Many people find it helpful to practice the test with control solution before testing with blood for the first time. See page 42 in the Control solution testing section.

#### Intended use

The OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood. The OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. It should not be used for the diagnosis of diabetes or for testing newborns.

#### **Test principle**

Glucose in the blood sample mixes with special chemicals in the test strip and a small electric current is produced. The strength of this current changes with the amount of glucose in the blood sample. Your meter measures the current, calculates your blood glucose level, displays the result, and stores it in its memory.

#### The OneTouch® Ultra® 2 Blood Glucose Monitoring System

Your new OneTouch® Ultra® 2 System Kit includes:

- a OneTouch® Ultra® 2 Meter (batteries included)
- b OneTouch® Ultra® Control Solution
- c OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler If another type of lancing device was included, see the separate instructions that came with that lancing device.
- d OneTouch® UltraClear® Cap
- e OneTouch® UltraSoft® Sterile Lancets
- f Carrying Case
- g You will also need OneTouch<sup>®</sup> Ultra<sup>®</sup> Test Strips. Some kits do not include strips. Strips are sold separately.

Documents in your kit include this owner's booklet, a quick reference guide, a control solution insert and a warranty registration card.

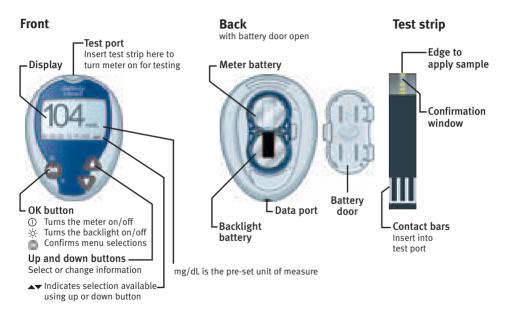
If any items are missing from your kit, call Customer Service.

**WARNING:** Keep the meter and testing supplies away from young children. Small items such as the battery door, batteries, test strips, lancets, protective disks on the lancets, and control solution vial cap are choking hazards.

С

#### Setting up your system

#### Getting to know your OneTouch® Ultra® 2 Blood Glucose Meter and test strips



#### Turning your meter on

To perform a test, insert a test strip as far as it will go. The meter will briefly perform system checks, then the display will turn on.

or,

With the meter turned off, press and hold in for two seconds to access MAIN MENU.

Check that the screen shows solid black for two

seconds. If it does, the display is working properly.

If the meter does not power on, try changing the meter battery. See page 51.

#### Using the meter display backlight

When the meter is already on, press and hold infortwo seconds to turn the backlight on or off.

#### Turning your meter off

There are several ways to turn your meter off:

- Press and hold 💿 for five seconds.
- Your meter will turn off by itself if left alone for two minutes.
- Go to MAIN MENU and press 🛆 or 👽 to highlight METER OFF, then press 💷.
- Before or after completing a test, remove the test strip. If you advance from the test result screen to the MAIN MENU by pressing , removing the strip will not turn the meter off. Use one of the three methods above.

CAUTION: If you see any light areas within the black start-up screen, there may be a problem with the meter. Call Customer Service. You can change many of the settings that came pre-set with your meter. Before using your meter for the first time or if you change the meter battery, you should check and update these settings. Make sure you complete steps 1 through 9 below to ensure your desired settings are saved.

#### 1. Turn the meter on, see page 3

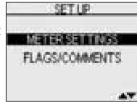
#### 2. Get to the LANGUAGE screen

When using the meter for the first time, or after changing the meter battery, you will automatically start in the LANGUAGE screen.

In other cases, from the MAIN MENU, press (a) or (b) to select SET UP. To confirm your selection, press (c). Then, press (a) or (c) to select METER SETTINGS. To confirm your selection, press (c).

The display now shows the LANGUAGE screen.





#### 3. Choose a language

Now press or  $rac{1}{2}$  to highlight the language of your choice. To confirm your selection, press .

The display now shows the DATE FORMAT screen.

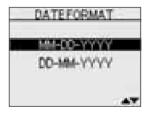
**NOTE:** If you select the wrong language, press and hold for five seconds to turn the meter off. Then, turn the meter back on and re-start from step 1.

#### 4. Set the date format

Press 🛆 or 👽 to highlight the date format choose month first (MM-DD-YYYY) or day first (DD-MM-YYYY). To confirm your selection, press 💽.

The display now shows the DATE SET UP screen.





#### 5. Set the date

In the DATE SET UP screen, press  $\triangle$  or  $\bigtriangledown$  to change the first value. To confirm your selection, press  $\bigcirc$ .

Press  $\triangle$  or  $\nabla$  to change the second value. To confirm your selection, press  $\bigcirc$ .

Press  $\triangle$  or  $\nabla$  to change the year. To confirm your selection, press

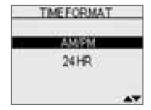


The display now shows the TIME FORMAT screen.

#### 6. Set the time format

Press 📥 or 👽 to select the time format you prefer—AM/PM or 24 HR. To confirm your selection, press 💿.

The display now shows the TIME SET UP screen.



**7. Set the hour** <u>and</u> **"AM" or "PM"** Press ▲ or **⊽** to set the hour.



Check AM/PM. If not correct, continue to press  $\triangle$  or  $\nabla$  until the hour <u>and</u> "AM" or "PM" are correct.

You can <u>ONLY</u> change "AM" and "PM" when you pass 12:00. Make sure "AM" or "PM" is correct while you are setting the hour.



Press 💿 to confirm your selection.

#### 8. Set the minutes

Press  $\triangle$  or  $\nabla$  to set the minutes.

Press 💿 to confirm your selection.

The display now shows the SETTINGS screen.

If "AM" or "PM" is not correct, press  $\triangle$  or  $\nabla$  to highlight "NO" and press to start over (Step 3 on page 5).

#### 9. Confirm your settings

The choice YES will be highlighted at the bottom of the screen. If your settings are correct, press to confirm and save the settings and return to the MAIN MENU.



▲ WARNING: The unit of measure mg/dL must be displayed here. If your display shows mmol/L rather than mg/dL, contact Customer Service. You cannot change the unit of measure. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

If you want to cancel your settings and start the settings process over again, press  $\triangle$  or  $\nabla$  to highlight NO and press  $\bigcirc$ . You will be returned to the LANGUAGE screen. Note that none of the settings you entered will be saved.

#### Turning the flags/comments feature off or on

Your OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter allows you to attach optional notes to any blood glucose test result. See pages 32–35 for the types of meal flags and comments you can attach to a result, and the reasons for using this feature. We suggest you talk to your healthcare professional to see how meal flags and comments may help you manage your diabetes.

Customer Service 1 800 227-8862

If you do not wish to track separate result averages for before and after meals, nor attach comments to any test result, you may turn this feature off.

If you turn off the flags/comments feature, you will not see ATT on the test result screen after you complete a blood glucose test. You will be able to review the ALL RESULTS AVG screen, but not before- or after-meal averages. See page 38 for more information about result averages.

To turn the flags/comments feature off or on:

### 1. From MAIN MENU, press $\bigtriangleup$ or ${\boldsymbol{\nabla}}$ to select SET UP

To confirm your selection, press 💿.

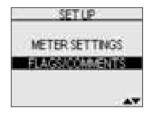
## 2. From the SET UP screen, select FLAGS/COMMENTS

To confirm your selection, press 💿.

#### 3. Press 🖾 or 👽 to highlight your response

Select YES if you wish to change the setting, or NO if you wish to leave it as it is.

Press 💿 to confirm your selection and return to MAIN MENU.





#### Starting the test process

Have these things ready when you test your blood glucose level:

- OneTouch® Ultra® 2 Meter
- OneTouch<sup>®</sup> Ultra<sup>®</sup> Test Strips
- Lancing device
- Sterile lancets with protective disks
- OneTouch<sup>®</sup> Ultra<sup>®</sup> Control Solution

#### NOTE:

- Use only OneTouch<sup>®</sup> Ultra<sup>®</sup> Test Strips with your OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter.
- Make sure your meter and test strips are about the same temperature before you test.
- Testing must be done within the operating temperature range (43–111°F). For the most accurate results, try to test as close to room temperature (68–77°F) as you can.
- OneTouch<sup>®</sup> Ultra<sup>®</sup> Test Strips are for single use only. Never re-use a test strip that had either blood or control solution applied to it.

▲ CAUTION: If you cannot test due to a problem with your testing supplies, contact your healthcare professional or Customer Service. Failure to test could delay treatment decisions and lead to a serious medical condition.

CAUTION: The test strip vial contains drying agents that are harmful if inhaled or swallowed and may cause skin or eye irritation.

## **1.** Check the code on the test strip vial before inserting the strip

Code numbers are used to calibrate your meter with the test strips you are using.

2. Insert a test strip to turn on the meter Start with the meter off. If you have turned the meter on to change settings or review past results, turn it off. Remove a test strip from its vial. With clean, dry hands, you may touch the test strip anywhere on its surface. Do not bend, cut or modify the test strips in any way. Use each test strip immediately after removing it from the vial.

Insert the test strip into the test port as shown. Make sure the three contact bars are facing you. Push the strip in as far as it will go. Do not bend the strip.

After the black start-up screen appears, the meter will display the code from your last test. If a flashing "——" appears instead of a code number, such as when you are first using the meter, follow the instructions on the next page to change to a numerical code.







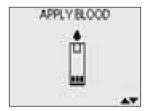
#### 3 Match the code on the meter with the code on the test strip vial

If the code on the meter does not match the code on the test strip vial, press a or 👽 to match the code number on the test strip vial. The new code number will flash on the display for three seconds, then briefly stop flashing, after which the display will advance to the APPLY BLOOD screen.

If the codes already match, press it go to the APPLY BLOOD screen. When you do not make a change after five seconds, the display will advance to the APPLY BLOOD screen.

The meter is now ready to perform a blood glucose test.

**CAUTION:** Matching the code on the meter and the code on the test strip vial is essential to obtaining accurate results. Each time you test, check to make sure the code numbers match.



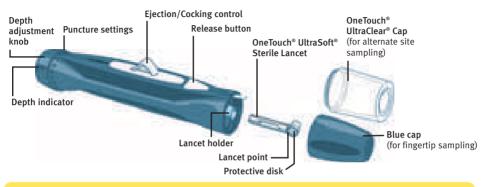


#### NOTE:

- If the APPLY BLOOD screen appears before you are sure the codes match, remove the test strip, and re-start from step 1, see page 11.
- If you change APPLY BLOOD to APPLY CONTROL by mistake, press 🐨 to change it back to APPLY BLOOD.

#### Getting a blood sample

#### Overview of the OneTouch® UltraSoft® Blood Sampler



**CAUTION:** To reduce the chance of infection:

- Make sure to wash the puncture site with soap and water before sampling.
- Never share a lancet or a lancing device with anyone.
- Always use a new, sterile lancet—lancets are for single use only.
- Keep your meter and lancing device clean. See pages 48–49.

**NOTE:** If you do not have a OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler, please refer to the instructions that came with your lancing device.

#### Choosing the right sampling site at the right time

The OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter allows you to sample blood from your fingertip, forearm or palm. At times, results obtained at the forearm or palm may be different from a fingertip measurement. Talk to your healthcare professional before you begin using your forearm or palm for sampling.

If you are testing:	Use blood sample from your:
Routinely before meals	Fingertip, forearm, or palm
<ul> <li>Prior to or more than two hours after:</li> <li>a meal</li> <li>a rapid-acting insulin injection or insulin pump bolus</li> <li>exercise</li> </ul>	Fingertip, forearm, or palm
<ul> <li>When your blood glucose is changing rapidly, such as:</li> <li>within two hours after a meal</li> <li>within two hours after a rapid-acting insulin injection or insulin pump bolus, or</li> <li>during or within two hours after exercise</li> </ul>	Fingertip
When you are concerned about the possibility of hypoglycemia (low blood sugar)	Fingertip

#### **CAUTION: Do not** test on your forearm or palm when:

- You think your blood glucose is rapidly falling, such as within two hours of exercise or a rapid-acting insulin injection or insulin pump bolus. Testing with a fingertip sample may identify hypoglycemia or an insulin reaction sooner than testing with a forearm or palm sample.
- It has been less than two hours after a meal, a rapid-acting insulin injection or insulin pump bolus, physical exercise, or you think your glucose level is changing rapidly.
- You are concerned about the possibility of hypoglycemia or an insulin reaction, such as when driving a car. This is especially important if you suffer from hypoglycemia unawareness (lack of symptoms to indicate an insulin reaction).

Remember: Consult with your healthcare professional before using your forearm or palm for testing.

Choose a different puncture site each time you test. Repeated punctures in the same spot may cause soreness and calluses.

If bruising occurs at an alternate site or you have difficulty getting a sample, consider sampling from a fingertip instead. You may want to review the choice of sites with your healthcare professional.

#### Preparing your sample site

Before you test your blood glucose, wash your hands and forearm (if applicable) thoroughly with warm, soapy water. Rinse and dry.

#### Lancing and sampling from your fingertip

1. Remove the blue cap by twisting it off





**2.** Insert a sterile lancet into the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler Insert the lancet into the holder and push in firmly. Twist the protective disk until it separates from the lancet and save the disk for later use. Do not twist the lancet.



3. Replace the blue cap by twisting it back on until it is snug

#### 4. Adjust the depth setting

If necessary, twist the depth adjustment knob toward the smaller dots on the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler for a shallow puncture or toward the larger dots for a deeper puncture.



Getting a blood sample

# Getting a blood sample

#### 5. Cock the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler

Slide the ejection/cocking control back until it clicks. If it does not click, it may have been cocked when you inserted the lancet.



#### 6. Puncture your finger

Hold the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler firmly against the side of your finger. Press the release button. Remove the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler from your finger.



**7.** Get a round drop of blood Gently squeeze and/or massage your fingertip until a round drop of blood **of at least one microliter** 

( actual size) forms on your fingertip.

If the blood smears or runs, do not use that sample. Dry the area and gently squeeze another drop of blood or puncture a new site.





#### Lancing and sampling from an alternate site

Sampling from your palm or forearm allows you to use your fingertips less often. You may find that obtaining a blood sample from an alternate site is less painful than using a fingertip. Getting a blood sample from your forearm or palm is different than getting a sample from your fingertips.

#### Forearm sampling

Choose a fleshy area of the forearm away from bone, visible veins and hair. Sometimes there is less blood flow to the forearm than to the fingertips. To help you get a large enough drop of blood, you may gently massage or apply warmth to the site to increase blood flow.

#### Palm sampling

Choose a fleshy area on the palm below your thumb or pinky finger. Select a spot with no visible veins and away from deep lines which may cause your blood sample to smear.



Forearm





Blue cap for fingertip sampling only

OneTouch<sup>®</sup> UltraClear<sup>®</sup> Cap is used for forearm and palm sampling only. Replace the blue OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler cap with the OneTouch<sup>®</sup> UltraClear<sup>®</sup> Cap.

#### 1. Remove the blue cap by twisting it off



#### 2. Insert a sterile lancet into the OneTouch® UltraSoft® Blood Sampler

Insert the lancet into the holder and push in firmly. Twist the protective disk until it separates from the lancet and save the disk for later use. Do not twist the lancet.



# Getting a blood sample

## **3.** Twist on the OneTouch® UltraClear® Cap until it is snug

#### 4. Adjust the depth setting

You may have to adjust the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler to a deeper setting to get a large enough drop of blood from your forearm or palm. Twist the depth adjustment knob toward the larger dots to increase the depth.

## 5. Cock the OneTouch® UltraSoft® Blood Sampler

Slide the ejection/cocking control back until it clicks. If it does not click, it may have been cocked when you inserted the lancet.







Press and hold the OneTouch® UltraSoft® Blood Sampler against your forearm or palm for a few seconds, then press the release button.

Keep holding the sampler and cap against your skin until a round drop of blood forms under the cap. Maintain pressure until the drop of blood is of **at least one microliter (** actual size).

#### 7. Remove the OneTouch® UltraSoft® Blood Sampler

Carefully lift the sampler away from your skin. Do not smear the blood sample.

#### NOTE:

• You may need to wait a little longer to get a large enough drop of blood from the forearm or palm. **Do not** squeeze the site excessively.



Forearm





- If the sample drop of blood runs or spreads due to contact with hair or with a line in your palm, **do not** use that sample. Try puncturing again in a smoother area.
- Remember: You may have to adjust the sampler to a deeper setting to get a large enough drop of blood (mactual size).
- 24 Customer Service 1 800 227-8862

#### Applying blood and reading results

Once you have a blood sample and your meter shows the APPLY BLOOD screen, you are ready to obtain a blood glucose result. If your meter does not show the APPLY BLOOD screen, remove the unused test strip and re-start the test process. See page 10.

#### 1. Prepare to apply the sample

The drop of blood should be next to the top edge of the test strip. Blood should not be applied to the flat face of the test strip.

When applying a drop of blood from your forearm or palm, keep your palm or forearm steady and bring the top edge of the test strip to the drop of blood with your other hand.



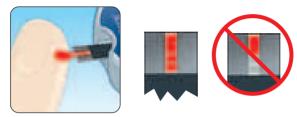
Fingertip

Forearm

25

#### 2. Apply the sample

Touch and hold the drop of blood to the narrow channel in the top edge of the test strip. Blood will be drawn into the strip. Keep holding the drop of blood to the top edge of the test strip until the confirmation window is full.



#### NOTE:

- Do not smear or scrape the drop of blood with the test strip.
- **Do not** press the test strip too firmly against your puncture site.
- **Do not** apply more blood to the test strip after you have moved the drop of blood away.
- **Do not** move the test strip in the meter during a test.

**CAUTION:** You may get an ERROR 5 message or an inaccurate result if the blood sample does not fill the confirmation window completely. See page 58. Discard the strip and re-start the test process.

When the meter detects blood in the test strip, it begins to count down from 5 to 1. Then, your blood glucose level appears on the display, along with the unit of measure, and the date and time of the test. Blood glucose results are automatically stored in the meter's memory.



**WARNING:** If mg/dL does not appear with the test result, call Customer Service. Use of the wrong unit of measure may cause you to misinterpret your blood glucose level, and may lead to incorrect treatment.

**CAUTION:** If you test at the low end of the operating range (43°F) and your glucose is high (over 180 mg/dL), the reading on your meter may be lower than your actual glucose. In this situation, repeat the test in a warmer environment with a new test strip as soon as possible.

#### **Error messages**

If you get an ERROR message on your screen rather than a result, see pages 53–59.

#### **Unexpected test results**

Refer to these cautions  $\triangle$  whenever your test results are lower than, higher than, or not what you expect.

#### **CAUTION:** Dehydration and low glucose results

You may get false low glucose results if you are severely dehydrated. If you think you are severely dehydrated, contact your healthcare professional immediately.

#### ▲ CAUTION: Low glucose results

If your test result is lower than 70 mg/dL or is shown as LOW GLUCOSE, it may mean hypoglycemia (low blood glucose). This may require immediate treatment according to your healthcare professional's recommendations. Although this result could be due to a test error, it is safer to treat first, then do another test.

#### **▲ CAUTION: High glucose results**

If your test result is higher than 180 mg/dL, it may mean hyperglycemia (high blood glucose). If you are uncertain about this test result, consider re-testing. Your healthcare professional can work with you to decide what actions, if any, you should take if your results are higher than 180 mg/dL.

If your meter displays HIGH GLUCOSE, you may have a very high blood glucose level (severe hyperglycemia) exceeding 600 mg/dL. Re-check your glucose level. If the result is HIGH GLUCOSE again, this may indicate a severe problem with your blood glucose control and it is important you obtain and follow instructions from your healthcare professional without delay.

#### ▲ CAUTION: Repeated unexpected glucose results

If you continue to get unexpected results, check your system with control solution. See Control solution testing, pages 42–46.

If you are experiencing symptoms that are not consistent with your blood glucose results and you have followed all instructions in this booklet, call your healthcare professional. Never ignore symptoms or make significant changes to your diabetes control program without speaking to your healthcare professional.

#### ▲ CAUTION: Unusual red blood cell count

A hematocrit (percentage of your blood that is red blood cells) that is either very high (above 55%) or very low (below 30%) can cause false results.

#### After getting a result

Once you have read your result, you may:

- Attach notes to this result if the flags/comments feature is on, see page 32, or
- Review your meter memory by pressing to go to MAIN MENU, see page 36, or
- Turn the meter off by removing the test strip.

#### Removing the used lancet

If you would like to cover the exposed lancet tip, remove the sampler cap by twisting it off. Then, place the lancet protective disk on a hard surface. Push the lancet tip into the disk.

To eject the lancet, point the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler down and away from you. Push the release button to ensure that the



sampler is not cocked. Push forward on the ejection/cocking control and the lancet will come out. Pull the ejection/cocking control to the middle position. Replace the cap.

## Disposing of the used lancet and test strip

It is important to discard the used lancet carefully after each use to avoid unintended lancet stick injuries. Used test strips and lancets may be considered biohazardous waste in your area. Be sure to follow your local regulations for proper disposal.

## Attaching flags or comments to your results

Your meter allows you to attach optional notes to your blood glucose result. There are two kinds of notes and different reasons to apply them.

Note type	Recommendation	Benefit
Meal flag	Add a meal flag to every blood glucose result.	Allows you to link the effects of food to your blood glucose results.
		Provides you with separate averages for before-meal and after-meal tests.
Comment	Select an appropriate comment whenever you test under conditions that you or your health- care professional feel are worth noting.	Helps track possible reasons for test results.

You can attach these notes just after a blood glucose test before you remove your used test strip from your meter. You can also modify notes when reviewing a past result.

You will not be able to add a meal flag or comment to a result marked as a control solution test.

You can choose not to attach a meal flag or comment after a blood glucose test. If you do not want to use this feature at all, you can turn it off so the meter will not prompt you to add notes or to select a type of result average to review. See page 9 for instructions.

## Add or change a meal flag

If the flags/comments feature is turned on, the up arrow at the bottom right corner of the result screen will flash when a result is first displayed to remind you to enter a meal flag. To add or change a meal flag:

# 1. While viewing a result, press $\Delta$ to display the MEAL FLAG screen

# 2. Press 💩 or 👽 to highlight BEFORE MEAL or AFTER MEAL

If you decide not to assign a flag to this result, select NO FLAG.



**3. To confirm your selection, press (a)** The meal flag you chose will appear above the result on the result screen.



**NOTE:** Testing after a meal can show how the food you ate affects your blood glucose. These results can be flagged as AFTER MEAL and are usually obtained two hours after the start of the meal. Your healthcare professional may suggest another time period or other use for this feature.

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## Add or change a comment

The down arrow at the bottom right corner of the result screen will flash after you enter a meal flag for a new result to remind you to consider entering a comment. To add or change a comment:

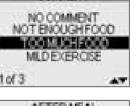
# 1. While viewing a result, press $\boldsymbol{\nabla}$ to display the COMMENT screen

## 2. Press 🖾 or 👽 to highlight an appropriate comment

The available choices are:

NO COMMENT	STRESS
NOT ENOUGH FOOD	ILLNESS
TOO MUCH FOOD	FEEL HYPO
MILD EXERCISE	MENSES (period)
HARD EXERCISE	VACATION
MEDICATION	OTHER

Highlight NO COMMENT if you decide not to add a comment, or if you want to erase a previously entered comment from the result.



COMMENT



Use OTHER when the available choices do not apply. You may want to write down what OTHER means to you so you can discuss it with your healthcare professional.

## 3. To confirm your selection, press 💿

The comment you chose will appear below the result.

# Reviewing past results and averages

If you have just completed a test, press to get to the MAIN MENU screen. If your meter is off, press and hold to turn it on. From the MAIN MENU screen you can choose:

- LAST RESULT to view your most recent result,
- ALL RESULTS to review up to 500 of your most recent results four at a time, or



• RESULT AVG to select one of three types of result averages.

Press  $\Delta$  or  $\nabla$  to highlight LAST RESULT, ALL RESULTS, or RESULT AVG.

To confirm your selection, press 💿

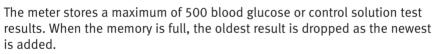
## Last result

The meter will display your most recent result. This result will include the unit of measure and the date and time of the test. If the result was marked as CONTROL SOLUTION or with either a meal flag or comment, these notes will be shown as well. Press to return to MAIN MENU. If you wish to add or change a meal flag or comment for this result, see pages 34-35.

## All results

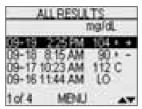
The meter will display four results at a time, in the order the tests were done, starting with the most recent. For each test result, the meter will display the date and time of the test. Results may also contain the following symbols:

- ${\rm HI}\,$  if the result was above 600 mg/dL,
- $\ensuremath{\text{LO}}$  if the result was below 20 mg/dL,
- $\star$  if a comment has been chosen for the result,
- **C** if the result is from a control solution test,
- if the result is flagged BEFORE MEAL, and
- + if the result is flagged AFTER MEAL.



To view details of an individual result, press  $\triangle$  or  $\bigtriangledown$  to highlight the result you want, then press  $\bigcirc$ . If you wish to add or change a meal flag or comment for this result, see pages 34–35. To return to the list of all results from an individual result, press  $\bigcirc$ .

To view more recent results, continue to press 📥 after the top result on the display is highlighted. If you press 📥 when the most recent result is highlighted, you will see the oldest stored results.



To view older results, press 👽 after MENU is highlighted. Pressing and holding 🛆 or 👽 allows you to move more quickly through the results. To return to the main menu, highlight MENU, then press 💿.

### **Result averages**

If the flags/comments feature is on, the meter will display the three types of averages you can access:

- the average of all test results,
- the average of before-meal results, and
- the average of after-meal results.

To select the type of result average you want to see, press  $\triangle$  or  $\nabla$  to highlight your choice, then press  $\bigcirc$ .



If you have turned the flags/comments feature off, selecting RESULT AVG from the MAIN MENU will lead directly to the ALL RESULTS AVG screen.

The meter will display each of your 7-, 14-, and 30-day averages. The top of the display shows which type of average you are looking at.

For each of the 7-, 14-, and 30-day periods leading up to the current date, the meter will display the number of results obtained (NUM) and the average of those results (AVG).

Reviewing past results and averages

In result averages, a HIGH GLUCOSE result is counted as 600 mg/dL, and a LOW GLUCOSE result as 20 mg/dL. Control solution results are not part of your averages.

From any screen showing averages, press on to go back to the previous screen.

To return to the main menu from the RESULT AVG screen,

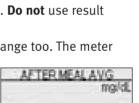
press  $\nabla$  until MENU is highlighted, then press to confirm your selection.

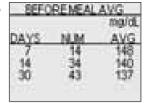
## NOTE:

- Result averages provide information from past results. **Do not** use result averages to make immediate treatment decisions.
- If you change your date setting, your averages may change too. The meter calculates averages based on the 7-, 14-, and 30-day periods ending on the current date setting.
- If you do not have results in the past 7-, 14-, and 30-day periods, the NUM and AVG columns will show 0. Also, if you do not use the meal flag feature, then the NUM and AVG columns will show 0 on the BEFORE MEAL and AFTER MEAL average screens.

To see averages for different parts of the day or over a different number of days, you can use OneTouch<sup>™</sup> Diabetes Management Software and your home computer. See the next section, on page 40.

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### Downloading results to a computer

You can use your meter with OneTouch<sup>™</sup> Diabetes Management Software (DMS) for storing your records and to help you spot patterns for planning meals, exercise, and medication. OneTouch<sup>™</sup> DMS puts information downloaded from the meter into charts and graphs.

## 1. Obtain the required software and cable

For order information and to learn more about OneTouch<sup>™</sup> Diabetes Management Software, visit www.OneTouchDiabetesSoftware.com

### 2. Install the software on a computer

Follow the installation instructions provided with the Software. If using a OneTouch<sup>™</sup> Interface Cable (USB format), install the software driver.

▲ WARNING: To avoid a possible shock, do not insert a test strip when the meter is connected to a computer with the OneTouch<sup>™</sup> Interface Cable.

## 3. Get ready to transfer readings

Connect the OneTouch  $\ensuremath{^{\scriptscriptstyle M}}$  Interface Cable to the COM or USB port on your computer.

Make sure the meter is turned off. If you insert the cable while the meter is already on, the meter will not respond to computer commands. Then connect the other end of the OneTouch<sup>™</sup> Interface Cable to the meter data port.



## 4. Transfer data

Follow the instructions provided with the OneTouch  ${}^{\scriptscriptstyle \rm M}{\sf DMS}$  to download the results from the meter.

Once the command to start the download is sent from the computer to the meter, the meter display will show "PC" indicating that the meter is in communication mode. You will not be able to perform a test when the meter is in communication mode.

## **Control solution testing**

OneTouch<sup>®</sup> Ultra<sup>®</sup> Control Solution contains a known amount of glucose and is used to check that the meter and the test strips are working properly.

Do a control solution test:

• to practice the test process instead of using blood,

once a week,

- whenever you open a new vial of test strips,
- if you suspect the meter or test strips are not working properly,
- if you have had repeated unexpected blood glucose results (as described on pages 28 and 29), or
- if you drop or damage the meter.

## NOTE:

- Use only OneTouch<sup>®</sup> Ultra<sup>®</sup> Control Solution with your OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter.
- Control solution tests must be done at room temperature (68–77°F). Make sure your meter, test strips, and control solution are at room temperature before testing.
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**CAUTION: Do not** swallow control solution; it is not for human consumption.

**Do not** apply control solution to the skin or eyes as it may cause irritation.

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#### Performing a control solution test

Start with the meter off. If you have turned the meter on to change settings or review past results, turn it off.

**1.** Check the code on the test strip vial before inserting the strip

**2. Insert a test strip to turn on the meter** Make sure the three contact bars are facing you. Push the strip in as far as it will go. Do not bend the strip.



# **3.** Match the code on the meter with the code on the test strip vial

If the code on the meter does not match the code on the test strip vial, press a or to match the code number on the test strip vial. The new code number will flash on the display for three seconds, then briefly stop flashing, after which the display will advance to the APPLY BLOOD screen.

If the codes already match, press into go to the APPLY BLOOD screen. When you do not make a change after five seconds, the display will advance to the APPLY BLOOD screen.

**4. Mark the test as a control solution test** Press to change APPLY BLOOD to APPLY CONTROL. You must mark the test before you apply control solution. Once you have completed the test, you cannot change the marking.

The meter is now ready to perform a control solution test.





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**5. Prepare and apply control solution** Shake the control solution vial before each test. Remove the cap and squeeze the vial to discard the first drop. Then wipe the tip with a clean tissue or cloth. Hold the vial upside down and gently squeeze a hanging drop.

Touch and hold the hanging drop of control solution to the narrow channel in the top edge of the test strip. Make sure the confirmation window fills completely. Control solution should not be applied to the flat face of the test strip.



## 6. Read your result

When the meter detects control solution in the test strip, it begins to count down from 5 to 1.

Your result will then appear on the display, along with the date, time, unit of measure, and the words CONTROL SOLUTION.

The control solution results can be viewed in the list of past results, but are not counted in your result averages.



## 7. Check if the result is in range

Compare the result displayed on the meter to the control solution range printed **on the test strip vial**. Each vial of test strips may have a different control solution range. If the results you get are not within this range, the meter and strips may not be working properly. Repeat the control solution test.



Out-of-range results may be due to:

- not following the instructions detailed on pages 42-45,
- expired or contaminated control solution,
- expired or damaged test strip,
- use of a test strip or control solution past its discard date, or
- a problem with the meter.

**CAUTION:** The control solution range printed on the test strip vial is for OneTouch<sup>®</sup> Ultra<sup>®</sup> Control Solution only. It is not a recommended range for your blood glucose level.

**CAUTION:** If you continue to get control solution test results that fall outside the range printed on the test strip vial, do not use the meter, the test strips, or the control solution. Call Customer Service.

# Caring for your system

Your OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Blood Glucose Monitoring System does not need any special maintenance.

#### Storing your system

Store your meter, strips, control solution and other items in your carrying case after each use. Store each item in a cool, dry place below 86°F, but do not refrigerate. Keep all items away from direct sunlight and heat.

Tightly close the cap on the test strip vial and/or control solution vial immediately after use to avoid contamination or damage. Store test strips only in their original vial.

**Checking for expiration or damage to strips and control solution** Test strips and control solution have expiration dates printed on their vials. When you first open a test strip or control solution vial, you must record the discard date (date opened plus three months) in the space provided on the label.

**CAUTION: Do not** use the strips or control solution after the expiration date printed on the vial or the discard date, whichever comes first, or your results may be inaccurate.

**CAUTION: Do not** use your test strips if your vial is damaged or left open to air. This could lead to error messages or tests that read higher than the actual value. Call Customer Service immediately if the test strip vial is damaged.

#### **Cleaning your meter**

To clean your meter, wipe the outside with a soft cloth dampened with water and mild detergent. Do not use alcohol or another solvent to clean your meter.

Do not get any liquids, dirt, dust, blood, or control solution inside the meter through the test port or the data port. Never spray cleaning solution on the meter or immerse it in any liquid.

# Cleaning your OneTouch $^{\circ}$ UltraSoft $^{\circ}$ Blood Sampler and OneTouch $^{\circ}$ UltraClear $^{\circ}$ Cap

To clean these items, wipe them with a soft cloth dampened with water and mild detergent. Do not immerse the OneTouch<sup>®</sup> UltraSoft<sup>®</sup> Blood Sampler in any liquid.

To disinfect these items, prepare a solution of one part household bleach to ten parts water. Wipe the OneTouch® UltraSoft® Blood Sampler with a soft cloth dampened with this solution. Immerse the **caps only** in this solution for 30 minutes. After disinfecting, rinse briefly with water and allow both to air dry.

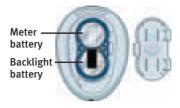
## **Batteries**

Your OneTouch® Ultra® 2 Meter uses two 3.0 Volt CR 2032 lithium batteries (or equivalent). Replacement batteries can be found in most stores where batteries are sold. Your meter comes with two batteries already installed —one that powers the meter only and one that powers the backlight.

#### Low meter battery

The meter shows a battery icon ( ) in the upper right corner of the display or a low battery message to indicate the condition of the **meter** battery only. When the battery icon first appears, there is enough power for a minimum of 100 more tests. You should replace the meter battery as soon as possible.

When your meter displays the LOW BATTERY screen message, there is not enough battery power remaining to perform a test. You must install a new battery before using your meter.





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## Low backlight battery

Replace the backlight battery when you can no longer see the backlight coming on. There will not be any icon on the meter display to indicate a low backlight battery. Note that the meter will provide accurate blood glucose results even when the backlight battery needs to be replaced.

## **Replacing batteries**

## 1. Remove the old battery

Start with the meter off. Open the battery door and pull up on the battery ribbon. The white ribbon is for the meter battery, and the black ribbon is for the backlight battery.

▲ WARNING: To avoid a possible shock, do not change either battery while the meter is connected to a computer with the OneTouch<sup>™</sup> Interface Cable.



battery Backlight \_\_\_\_\_ battery

## 2. Insert the new battery

With the "+" side facing up toward you, place the battery in the compartment within the fold of the ribbon. Push the battery until it snaps into the battery clasp. Insert the two battery door tabs into the matching holes on the meter, and push down until you hear the door click into place.



If the meter does not power on after you have replaced the meter battery, check that the battery is correctly installed with the "+" side up. If the meter still does not power on, call Customer Service.

#### 3. Check your meter settings

Removing the meter battery will not affect your stored results. However, you may need to re-set your meter settings. See pages 4–8.

# 4. Dispose of batteries according to your local environmental regulations

# Understanding error and other messages

The OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter displays messages when there are problems with the test strip, with the meter, or when your blood glucose levels are higher than 600 mg/dL or lower than 20 mg/dL. Messages do not appear in all cases when a problem has occurred. Improper use may cause an inaccurate result without producing an error message.

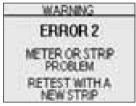
Message	What it means	What to do	
WARNING LOW GLUCOSE BELOW 20 mg/dL	You may have a very low blood glucose level (severe hypoglycemia), lower than 20 mg/dL.	This may require immediate treatment according to your healthcare professional's recommendations. Although this message could be due to a test error, it is safer to treat first and then do another test.	

Message	What it means	What to do
WARNING HIGH GLUCOSE ABOVE 600 mg/dL	You may have a very high blood glucose level (severe hyperglycemia), over 600 mg/dL.	Re-check your glucose level. If the result is HIGH GLUCOSE again, obtain and follow instructions from your healthcare professional without delay.



Meter is too hot (above 111°F) or too cold (below 43°F) to work correctly. Wait a few minutes and insert a new test strip. If you do not get another TEMPERATURE ERROR message, the meter is now within the operating range.

Message	What it means	What to do
WARNING ERROR 1 METER PROBLEM	There is a problem with the meter.	Do not use the meter. Contact Customer Service.
CALL CUSTOMER SERVICES		



Error message could be caused either by a used test strip or a problem with the meter. Repeat the test with a new test strip; see pages 25–27. If this message continues to appear, contact Customer Service.

Message	What it means	What to do	
WARNING         ERROR 3         METER WASNOT READY         RETEST WITH A         NEW STRIP		Repeat the test with a new test strip. Apply a blood or control solution sample only after APPLY BLOOD or APPLY CONTROL appears on the display. If this message continues to appear, contact Customer Service.	
WARNING ERROR 4	One of the following may apply: You may have high	If you tested in a cool	

glucose and have

environment near

the low end of the

system's operating

temperature range (43–111°F).

tested in an

Understanding error and other messages

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or,

STRIPPROBEN

If you tested in a cool environment, repeat the test in a warmer environment with a new test strip; see pages 25–27. If the error message appears again, contact Customer Service.

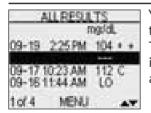
Error 4 information continues on next page

Message	What it means	What to do
WARNING ERROR 4 STRIPPROBLEM SEE OWNER'S BOOKLET	There may be a problem with the test strip. For example, it may have been damaged or moved during testing. <i>or</i> ,	If you tested in a normal or warm environment, repeat the test with a new test strip; see pages 25–27. If the error message appears again, contact Customer Service.
	The sample was improperly applied. <i>or,</i>	If you applied the blood incorrectly, review pages 25–27 on blood application and repeat the test with a new test strip. If the error message appears again, contact Customer Service.
	There may be a problem with the meter.	If the error message appears again, contact Customer Service.

Error 4 information begins on previous page

Message	What it means	What to do
WARNING ERROR 5 STRIP PROBLEM OR SAMPLE TOO SMALL RETEST WITH A NEW STRIP	The meter has detected a problem with the test strip. Possible causes are test strip damage or an incompletely filled confirmation window.	Repeat the test with a new test strip. Refer to pages 25–27 for information on sample application.
10-08-05 11:15 AM	Meter battery is low but still has enough power to perform a test.	When the battery icon first appears, there is enough power for a minimum of 100 more tests. Test results will still be accurate, but replace the battery as soon as possible.
WARNING EX LOW BATTERY REPLACE BATTERY NOW SEE OWNER'S BOOKLET	Meter battery does not have enough power to perform a test.	Replace meter battery.

Message	What it means	What to do
	No result in memory, such as the first time use of the meter or after a download of all data to a computer. <i>or</i> , Your meter was unable to recall this result. This result will not be included in result averages.	<ul> <li>You can still perform a blood glucose test and get an accurate result. Contact Customer Service to report this occurrence if this is <b>not</b>:</li> <li>1. Your first time use of the meter, or</li> <li>2. After you just downloaded results from your meter.</li> </ul>



Your meter was unable to recall this result. This result will not be included in result averages. You can still perform a blood glucose test and get an accurate result, but contact Customer Service to report this occurrence.

# Detailed information about your system

## Comparing meter and laboratory results

Test results with the OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter are plasma-calibrated. This helps you and your healthcare professional to compare your meter results with laboratory tests. If you have been using another type of meter—one that provides whole-blood-calibrated results—you may notice that your test results with the OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter are approximately 12% higher.

OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter test results and laboratory test results both are expressed in plasma-equivalent units. However, your meter result may differ from your laboratory result due to normal variation. Meter results can be affected by factors and conditions that do not affect laboratory results in the same way.

Your OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter glucose value is considered accurate when it is within  $\pm 20\%$  of the laboratory measurement. There are some specific situations that could cause a difference of more than  $\pm 20\%$ :

• You have eaten recently. The blood glucose level from blood obtained from a fingertip can be up to 70 mg/dL higher than blood drawn from a vein (venous sample) used for a lab test.<sup>1</sup>

<sup>1</sup> Sacks, D.B.: "Carbohydrates." Burtis, C.A., and Ashwood, E.R. (ed.), *Tietz Textbook of Clinical Chemistry*. Philadelphia: W.B. Saunders Company (1994), 959.

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- Your hematocrit (percentage of your blood that is red blood cells) is high (above 55%) or low (below 30%).
- You are severely dehydrated.
- You tested at a temperature near the low end of the operating range (43°F) and you get a high glucose result (i.e., greater than 180 mg/dL). In this situation, repeat the test in a warmer environment with a new test strip as soon as possible.

For accuracy and precision data and for important information on limitations, see the insert that comes with your test strips.

To maximize your chances of an accurate comparison between meter and laboratory results, follow a few basic guidelines:

## Before going to the lab

- Perform a control solution test to make sure the meter is working properly.
- Do not eat for at least eight hours before you test your blood.
- Take your meter with you to the lab.

## While at the lab

- Conduct your meter test within 15 minutes of the lab test.
- Use only fresh, capillary blood obtained from the fingertip.
- Follow all instructions in this owner's booklet for performing a blood glucose test with your meter.

## **Technical specifications**

Reported result range	20-600 mg/dL
Calibration	Plasma-equivalent
Sample	Fresh capillary whole blood
Sample size	Minimum 1 microliter
Test time	5 seconds
Assay method	Glucose oxidase biosensor
Meter power source	One replaceable 3.0 Volt CR 2032 lithium battery (or equivalent)
Backlight power source	One replaceable 3.0 Volt CR 2032 lithium battery (or equivalent)
Unit of measure	mg/dL
Memory	500 blood glucose or control solution test results
Automatic shutoff	2 minutes after last action
Size	3.12 x 2.25 x 0.90 inches
Weight	Approximately 1.5 ounces, with batteries

Detailed information about your system

Operating ranges	Temperature: 43–111°F Relative humidity: 10–90% Altitude: up to 10,000 feet Hematocrit: 30–55%
Battery ratings	2 x 3.0 V d.c., 60 mA (2 x CR 2032 batteries) direct current

## Symbols

Cautions and Warnings. Refer to safety-related notes in the owner's booklet and inserts that came with your meter and testing supplies.

Low battery

Direct current

## Guarantee

LifeScan guarantees that the OneTouch<sup>®</sup> Ultra<sup>®</sup> 2 Meter will be free of defects in material and workmanship for three years, valid from the date of purchase. The guarantee extends only to the original purchaser and is not transferable.

## **Electrical and safety standards**

This meter complies with CISPR 11: 2003. Class B (Radiated Only). Emissions of the energy used are low and not likely to cause interference in nearby electronic equipment.

The meter has been tested for immunity to Level 3 electrostatic discharge as specified in IEC 61000-4-2.

This meter has been tested for immunity to radio frequency interference over the frequency range 80MHz to 2.5GHz at 3V/m as specified in IEC 61000-4-3

Degree of protection rating: IP32



(G) CAN/CSA C22.2 61010-1:04, UL 61010-1:04, IEC 61010-1 and <sup>c</sup> <sup>us</sup> IFC 61010-2-101.

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Reminders
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Before lunch or dinner	
1 hour after meals	
2 hours after meals	
Between 2 a.m. and 4 a.m.	

#### **Patent information**

The system described herein is covered by one or more of the following U.S. patents: 5,708,247, 5,951,836, 6,045,567, 6,156,051, 6,197,040, 6,241,862, 6,284,125, and D 428,150. Use of the monitoring device described herein is protected under one or more of the following U.S. patents: 6,413,410, 6,733,655. Purchase of the monitoring device described herein does not act to grant a use license under these patents. Such a license is granted only when the device is used with OneTouch<sup>®</sup> Ultra<sup>®</sup> Test Strips. No test strip supplier other than LifeScan, Inc. is authorized to grant such a license. The accuracy of results generated with LifeScan meters using test strips manufactured by anyone other than LifeScan has not been evaluated by LifeScan.

Call Customer Service toll-free, 24 hours a day, 7 days a week

English **1 800 227-8862** Español **1 800 381-7226** Or Visit us at www.LifeScan.com





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